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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,119	11/25/2003	Michel H. Malek	036163-0103	4839

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EXAMINER	
COMSTOCK, DAVID C	
ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
04/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,119	MALEK, MICHEL H.	
	Examiner	Art Unit	
	DAVID COMSTOCK	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 43* is/are pending in the application.

4a) Of the above claim(s) *3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-25 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-12, 16-25 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Alby (6,241,730).

Alby discloses the claimed invention including a stabilizing element comprising first and second segments, e.g., 4A, 4B connected by a pivoting joint, e.g., 4 (see, e.g. Fig. 1-3). Connectors such as bone screws (not shown) are adapted to connect the stabilizing element to vertebra (see col. 2, line 67). The segments comprise a pin style ball and socket connection comprising damping elements, e.g., 12 around a neck. A flat strip 11 extends around a midsection. The joint comprises opposing concave and convex surfaces (e.g. lateral edges of the strip and the surface opposing convex ball end of pin 4Ba). Opposing threads can be characterized as windows and tabs, as they define openings or windows to their minor diameter and small extensions or tabs to their major diameter (see, e.g., Fig. 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alby (6,241,730) in view of Crozet et al. (6,217,578).

Alby discloses the claimed invention except for explicitly reciting the use of cross-connectors. Crozet et al. disclose a system for treating vertebrae comprising the use of cross-connectors to "provide enhanced stability" to other spinal systems and improve the treatment of the spine (see, e.g., col. 7, lines 29-36). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the intervertebral link device of Alby with a cross-connector, in view of Crozet et al., in order to provide enhanced stability to the device of Alby and improve the treatment of the spine. It is noted that the use of a cross connector on single ends of the device set forth by Alby would provide the advantage of additional stability as taught by Crozet, while still allowing for relative motion with respect to the other ends of the device of Alby. Moreover, it is predictable that both of these known systems would be combined for their stated purposes and advantages (reduced mechanical stresses and enhanced stability).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alby (6,241,730) in view of Karpman et al. (6,214,012).

Alby discloses the claimed invention except for explicitly reciting the use of a tissue growth-resistant material. Karpman et al. teach that bone cement can be used to enhance the fixation of screws in bone (see, e.g., col. 9, lines 28-44). Therefore, it would have been obvious to a person having ordinary skill in the art to install the screws of Alby with bone cement, in view of Karpman et al., in order to enhance the fixation of the screws in bone and reduce the chance of them coming loose. (Bone cement is a tissue growth-resistant material as evidenced by McLeer, US 2006/0079895 A1, paragraph 46. It is noted that a person having ordinary skill in the art would have been motivated to use bone cement for the reason provided by Karpman et al.; McLeer simply evidences that bone cement meets the limitation in Applicant's claim regarding the use of a substance that inhibits tissue growth.) Moreover, it also would have been obvious to have provided the device of Alby with a tissue growth-resistant material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed 02 January 2008 have been fully considered but they are not persuasive.

In response to Applicant's argument regarding the Alby reference, it is noted that the specification must clearly set forth the definition of "disc prosthesis" or "disc nucleus replacement" explicitly and with reasonable clarity, deliberateness, and precision.

Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001), and MPEP 2111.01. Here, for example, it is noted that the device of Alby clearly replaces a disc nucleus and satisfies such claim terminology. Moreover, it is noted that fusion between two vertebrae does not prevent "mobility of the spine," since there are many joints in a spine and the fusion of one of such joints cannot be said to prevent mobility of the spine. Next, regarding McLeer, this reference was not relied upon as the basis of the rejection, it is simply cited to evidence that bone cement is a tissue growth-resistant material. Regarding Karpman et al., it is noted that the claim sets forth that the growth-resistant material need only be "around" the joint, not directly on it. Therefore, its use does not preclude any movement of the joint. Moreover, at the interface of the cement region and any other region, ingrowth would be inhibited.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. Please leave a detailed voice message if examiner is unavailable. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/DC/

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733